IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of : Group Art Unit: 1615
ERNING XIA et al. : Examiner: BETHANY P. BARHAM
Serial No. 10/725,159
Filed: December 1, 2003
For: GENTLE AND ENHANCED PRESERVATIVE SYSTEMS
Attorney Docket No. P03366

BRIEF ON APPEAL

HONORABLE COMMISSIONER OF PATENTS
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants filed a notice of appeal for the above-identified application on May 20, 2008, appealing the final rejection of claims 4, 7, 9-12, 20 and 21. In accordance with 37 C.F.R. § 41.37, an appeal brief is set forth below and submitted. A copy of claims 4, 7, 9-12, 20 and 21 is annexed hereto and labeled "Appendix."

I. Real Party in Interest

The real party in interest for the above-identified patent application is Bausch & Lomb Incorporated, the employer of the inventors named in the present invention. The named inventors have assigned their entire right, title, and interest in the present invention to Bausch & Lomb Incorporated.

II. Related Appeals And Interferences

There are no known related appeals and interferences that will directly affect or be affected by or have a bearing on the Board's decision in the instant appeal.

III. Status of the Claims

Claims 4, 7, 9-12, 20 and 21 are pending.

Claims 4, 7, 9-12, 20 and 21 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Hu et al. (U.S. Patent 6,274,133; hereinafter "Hu") in view of Sugiura (U.S. Patent 5,928,606).

IV. Status of Amendments

Appellants filed a response to the final Office action, without amending the claims, dated April 25, 2008, two months after the date of the final Office action. In that response, Appellants respectfully presented arguments that a combination of Hu and Sugiura does not teach or suggest all of the limitations of each of the pending claims, and thus, the claims are patentable over Hu and Sugiura under 35 U.S.C. § 103(a). In the Advisory action dated May 9, 2008, the Examiner maintained the rejection of the claims because, among other things, she still failed to see or acknowledge the difference between a wetting agent, which is taught by the prior art, and a preservative, which is claimed in the pending claims.

V. Summary of the Invention

The present invention provides a method of imparting a preservative efficacy to a solution that is usable for treating a medical device in general, and a contact lens in particular, and, unlike other prior-art solutions, is non-irritating to the tissues that come into contact with such solution. The method of the present invention comprises providing in such solution one or more saccharides selected from the group consisting of glucose and α-methyl gluco-pyranoside in their D or L forms in combination with one or more polyquaternium-10 cationic polysaccharides, wherein the saccharides and cationic polysaccharides are in amounts effective for solution preservation. The present invention is a long-awaited advance in the search for gentle preservatives for ophthalmic formulations that would avoid an often complained side effect of discomfort to the eye when such formulations come into contact with a surface of the eye. Traditional preservatives for ophthalmic formulations include the ammonium salts (e.g., benzalkonium chloride, chlorhexidne), oxidizing agents, and aromatic alcohols. In contrast, the present invention

uniquely and advantageously uses a combination of a sugar and a sugar derivative, which are gentle to the eye tissues, and thus successfully addresses a long-felt need.

VI. Issues Presented

The only issue that must be resolved in this appeal is whether claims 4, 7, 9-12, 20 and 21 are patentable under 35 U.S.C. § 103(a) over Hu in view of Sugiura.

VII. Grouping of the Claims

For each ground of rejection which Appellants contest herein which applies to more than one claim, such additional claims, to the extent separately identified and argued below, do not stand or fall together.

VIII. The Argument

Issue -- Whether 4, 7, 9-12, 20 and 21 are patentable under 35 U.S.C. § 103(a) over Hu in view of Sugiura.

Claims 4, 7, 9-12, 20 and 21 are patentable under 35 U.S.C. § 103(a) over Hu in view of Sugiura because a combination of Hu and Sugiura does not teach or suggest all the elements of each of claims 4, 7, 9-12, 20 and 21.

Obviousness requires a suggestion of all the elements in a claim and a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does. *Ex parte Alexander*, 86 U.S.P.Q.2d 1120, 1122 (BPAI, Nov. 30, 2007) (quoting *CFMT, Inc. V. Yieldup Int'l Corp.*, 349 F.3d 1333, 1342 (Fed. Cir. 2003) and *KSR Int'l Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1741 (2007)) (emphasis added). It is fatal to the rejection when "the Examiner has not identified all the elements of [a] claim [or] provided a reason that would prompted the skilled worker to have arranged them in the manner necessary to reach the claimed invention." *Id.*

Here, each of claims 4, 7, 9-12, 20, and 21 recites a method of imparting preservative efficacy to an ophthalmic solution by providing in the solution one or more saccharides selected from the group consisting of glucose and α-methyl gluco-pyranoside in

their D or L forms in combination with one or more polyquaternium-10 cationic polysaccharides, wherein the saccharides and cationic polysaccharides are in amounts effective for solution preservation. Nowhere in the combined disclosure of Hu and Sugiura Patent is found such a combination of the recited ingredients together, present in amounts effective for solution preservation. The Examiner has ignored this element of each of the claims. Moreover, the Examiner has not offered any rationale that the use of mono or disaccharides or ethoxylated glucose (Hu, claim 5) as wetting agents and cationic cellulosic polymers (Hu, column 5, lines 13-16) as inhibitors of lipid deposition on contact lens surface would be the same as a combination of glucose or α-methyl gluco-pyranoside and polyquaternium-10 as preservative, as recited in the pending claims. Nor has the Examiner offered any rationale why such wetting agents and inhibitors of lipid deposition of Hu may be combined with the use of glucose or mannitol as tonicity agents in Sugiura (see; e.g., Sugiura, column 10, lines 48-51) to arrive at a combination of glucose or α-methyl gluco-pyranoside and polyquaternium-10 as preservative, as recited in the pending claims.

As the Supreme Court admonished in *KSR Int'l Co.*, 127 S.Ct. at 1741, "a patent composed of several elements is not proved obvious merely by demonstrating that each element [note that "element" means limitation of the claims, not merely physical ingredient] was, independently, known in the prior art. . . . [I]t can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed invention does." (Emphasis added.) Here, the Examiner has not articulated any reason why a person of ordinary skill would use a wetting agent, an inhibitor of lipid deposition, and a tonicity agent (the prior art) as a preservative (the claimed invention).

Since a combination of Hu and Sugiura does not teach or suggest that glucose or α-methyl gluco-pyranoside and polyquaternium-10 as preservative and since the Examiner has not set forth any rationale why the taught wetting agents, inhibitors of lipid deposition, and tonicity agents would be used as preservative, claims 4, 7, 9-12, 20 and 21 are patentable under 35 U.S.C. § 103(a) over Hu in view of Sugiura.

In addition, the Examiner has misunderstood the teaching of the prior art. The Examiner asserted that Hu discloses saccharides as suitable wetting agents (in claim 5 of this patent) and that Sugiura teaches the wetting agents including saccharides such as

glucose (Office action dated February 25, 2008 (hereinafter "Office action"), page 3, citing col. 10, lines 36-52 of the '606 Patent). First of all, the Examiner's latter assertion is not even correct. Sugiura, at the section cited by the Examiner, does not teach that saccharides were wetting agents. Instead, Sugiura teaches that saccharides were examples of tonicity agents. People of ordinary skill in the art understand that tonicity agents generally are not wetting agents. Moreover, the Examiner has not set forth the reason why she considered tonicity agents to be preservatives. Tonicity agents are compounds that are used to adjust the osmolality of a solution (most often are inorganic salts, glycerine, or some limited monosaccharides). On the other hand, preservatives are compounds that prevent the growth of microorganisms.

The Appellants did not argue that Hu and Sugiura do not disclose wetting agents. Nor did the Appellants argue against each cited patent separately. Instead, the Appellants argued that the combination of these patents does not disclose all the elements of each of the claims (i.e., including the combination used as preservative). Specifically, the combination of these patents does not teach that the recited ingredients are included in a composition of the claims in amounts effective for solution preservation. The Examiner has not pointed to any part of the cited patents as proof of disclosure of such claimed limitation. Nor did the Examiner explain on the record why the teaching of separate wetting agents amounts to the teaching of the same compounds in combination with polyquaternium-10 in quantities effective as preservatives. When there is no teaching that a prior-art element would be useful in the claimed system, and a fair reading of the combined prior art disclosures teaches only the system of one of the references, the Examiner's strained consideration of these combined teachings would be a hindsight reconstruction of Appellants' claimed invention. *Ex parte van Ostrand*, BPAI, January 30, 2008.

Regarding the pending dependent claims, since a combination of the cited patents does not teach or suggest the combination of a cationic polysaccharide and one or more saccharides selected from the group consisting of glucose and α-methyl gluco-pyranoside in their D or L forms in amounts effective for solution preservation, as recited in each of independent claims 20 and 21, pointing out that the cited prior art also discloses disparately other ingredients recited in dependent claims 4, 7, and 9-12 still does not cure the deficiency of the 103(a) rejection.

Moreover, claims 4, 7, 9-12, 20 and 21 are patentable under 35 U.S.C. § 103(a) over Hu in view of Sugiura because a person of ordinary skill would not be expected to use a sugar as preservative to inhibit the growth of microorganisms.

At least some degree of predictability that the combination or modification would be successful is required. Evidence showing there was no reasonable expectation of success may support a conclusion of nonobviousness. *In re Rinehart*, 189 U.S.P.Q. 143 (Fed. Cir. 1976).

It is known that microorganisms need a source of energy and moisture to grow. Sugars, including glucose or derivatives thereof, are known to be good sources of energy for microorganisms (as evidenced by the fact that agar has been used for bacterial culture). Thus, a person of ordinary skill would not have used glucose in an aqueous solution as part of a preservative. However, the Appellants proceeded against the conventional wisdom and demonstrated that a combination of glucose or α-methyl gluco-pyranoside and polyquaternium-10 (a derivative of cellulose, another sugar derivative) provided good preservative efficacy for the solution.

Since a person of ordinary skill not expect success in using glucose as an ingredient of a preservative system for a solution, claims 4, 7, 9-12, 20 and 21 are patentable under 35 U.S.C. § 103(a) over Hu in view of Sugiura.

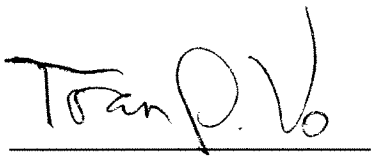
In addition, the Appellants respectfully traverse the Examiner's reading that Sugiura's discussion of disinfection amounts to the same as preservation. Sugiura listed the following disinfectants, which are non-sugar materials: polyhexamethylene biguanide hydrochloride salt (PHMB), a solution of chlorhexidine having a guanidine group, benzalkonium chloride, benzethonium chloride (Sugiura, column 6, lines 20-23), quaternary ammonium salts, guanidine, guanidine disinfectant in which a coupling group is introduced, such as: chlorhexidine, or chlorhexidine in which the coupling group is introduced; 1,17-diguanidino-9-aza-heptadecane, or 1,17-diguanidino-9-aza-heptadecane in which the coupling group is introduced; and polyhexamethylene biguanide, or polyhexamethylene biguanide in which the coupling group is introduced (Sugiura, column 6, lines 57-67). First, these are non-sugar materials. Second, the capacity and requirement for disinfection is not the same as those for preservation. Concentrations of these materials for disinfection

user's eyes. Thus, without a teaching or suggestion or a reason of why a discussion of non-sugar materials may be extended to sugar and sugar derivatives, Sugiura's materials cannot form a basis for a Section 103(a) rejection of the claimed method.

IX. Conclusion

For the reasons set forth above, Appellants respectfully submit that claims 4, 7, 9-12, 20 and 21 are patentable and should be allowed. Appellants respectfully request that the Honorable Board of Patent Appeals and Interferences reverse the Examiner's final rejection and hold claims 4, 7, 9-12, 20 and 21 allowable.

Respectfully submitted,



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APPENDIX

The Claims on Appeal

Claim 4 (Previously Presented): The method of claim 20, wherein said one or more cationic polysaccharides are selected from the group consisting of polyquarternium-10.

Claim 7 (Previously Presented): The method of claim 21, wherein said one or more cationic polysaccharides are selected from the group consisting of polyquarternium-10.

Claim 9 (Previously Presented): The method of claim 20 or 21 wherein said solution includes one or more buffers or buffering systems.

Claim 10 (Previously Presented): The method of claim 20 or 21 wherein said solution includes one or more tonicity agents.

Claim 11 (Previously Presented): The method of claim 20 or 21 wherein said solution includes one or more surfactants.

Claim 12 (Previously Presented): The method of claim 20 or 21 wherein said solution includes one or more viscosity agents.

Claim 20 (Previously Presented): A method of imparting a preservative efficacy to a contact lens solution, the method comprising:

providing in said contact lens solution a preserving agent that comprises one or more saccharides selected from the group consisting of glucose and α-methyl gluco-pyranoside in their D or L forms in combination with one or more polyquaternium-10 cationic polysaccharides, wherein the saccharides and cationic polysaccharides are in amounts effective for solution preservation.

Claim 21 (Previously Presented): A method of imparting a preservative efficacy to a solution that is usable for treating a medical device, the method comprising:

providing in said solution a preserving agent that comprises one or more saccharides selected from the group consisting of glucose and α-methyl gluco-pyranoside in their D or L forms in combination with one or more polyquaternium-10 cationic polysaccharides, wherein the saccharides and cationic polysaccharides are in amounts effective for solution preservation.